

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
COLUMBIA DIVISION**

UNITED STATES OF AMERICA,

Plaintiff,

ex rel. JON VITALE,

Relator,

v.

MIMEDX GROUP, INC.,

Defendant.

CA No. 3:17-cv-00166-RBH

**Relator’s notice of supplemental authority and
suggestions in opposition to motion to dismiss**

In United States ex rel. Grant v. United Airlines Inc., No. 17-2151, 2018 WL 6786134 (4th Cir. Dec. 26, 2018), the Fourth Circuit explained “there are two ways to adequately plead presentment under Rule 9(b).” Id. at *3 (attached as **Exhibit A**). A plaintiff can (1) allege with particularity that specific false claims were presented for payment—i.e., the person, time place, and contents of the false representation and what was obtained thereby—or (2) allege a pattern of conduct that would necessarily have led to the submission of false claims. Id. (quoting United States ex rel. Nathan v. Takeda Pharm. N. Am., Inc., 707 F.3d 451, 457 (4th Cir. 2013) and United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008)). Thus, Grant clarifies that Nathan should be read to recognize at least *two* ways to plead presentment with particularity. Relator Jon Vitale respectfully gives notice of this supplemental authority and offers the following suggestions in support of his memorandum in opposition (Dkt. No. 66) to Defendant MiMedx Group, Inc.’s (MiMedx’s) pending motion to dismiss (Dkt. No. 65).

SUGGESTIONS IN SUPPORT OF DENYING MOTION TO DISMISS

MiMedx has urged dismissal, at least in part, because of some perceived shortcoming under Rule 9(b) of the federal rules. See Dkt. No. 65 at 1 & Dkt. No. 65-1 at 11–22. For instance, MiMedx argued, “Here, Relator utterly fails to identify any specific false claim that was presented to the government for payment as a result of MiMedx’s purported kickback scheme” and argues Mr. Vitale “fails to plead any facts linking MiMedx’s donations with any specific PAN charitable award and subsequent claim for payment.” Dkt. No. 65-1 at 20. In response, Mr. Vitale corrected MiMedx’s misapprehension of Rule 9(b)’s pleading requirement, explaining the Complaint describes the who, what, when, and how of the fraud backed by Mr. Vitale’s first-hand knowledge and MiMedx records, including a *specific* example of a patient whose Medicare Part D coinsurance payment was paid as a result of the scheme. See Dkt. No. 66 at 2 & 6–11 (citing United States ex rel. Nathan v. Takeda Pharmaceuticals North America, Inc., 707 F.3d. 451, 454–58 (4th Cir. 2013); United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 379 (4th Cir. 2008); United States v. Berkeley Heartlab, Inc., 225 F. Supp. 3d 487, 505 (D.S.C. 2016)). Thus, the Complaint describes a scheme that necessarily led to the submission of false claims *and* provides a specific example of a Medicare beneficiary with kickback-tainted care:

Mr. Vitale’s claims are plausible because, as a sales representative, he received direction—some in the form of written correspondence attached to the Complaint—in furtherance of the scheme. See Dkt. No. 1-1 & 1-2. MiMedx’s executives also alerted him and his colleagues of when the PAN Foundation fund would open and close (Dkt. No. 1-3, 1-5 & 1-6) which, at a minimum, gives rise to a strong inference of impropriety if it does not corroborate these allegations outright. Finally, if any doubt remains whether the submission of false claims is the necessary, foreseeable, and obvious consequence of this scheme, the Complaint does what Nathan explains will always render a pleading plausible and particular by identifying a specific federally insured patient whose coinsurance was illegally paid as a result of this scheme and furnishes documentary evidence to corroborate this allegation. See Dkt. No. 1-7. MiMedx has sufficient notice of the claims at issue and the Complaint meets the requirements of Rules 8 and 9(b).

Dkt. No. 66 at 6–11 (footnote omitted); see also id. at 2 (“Were there any doubt that this scheme has resulted in the submission of false claims, included within the allegations is a *specific* example of a patient whose Medicare Part D coinsurance payment was paid as a result. See Dkt. No. 1 at ¶ 156 & Dkt. No. 1-7 (Ex. G).” (emphasis original)). In reply, MiMedx disparaged the significance of Mr. Vitale’s ability to identify an individual Medicare beneficiary as insufficient to establish the presentment of a false claim (see Dkt. No. 67 at 11–12) but provided no authority for its distinction. Grant makes clear that this claim satisfies Rule 9(b).

In Grant, the relator alleged that his employer, a military sub-subcontractor responsible for maintaining and repairing jet engines, (1) falsely certified repairs had occurred; (2) certified repairs that occurred with uncalibrated and uncertified tools; and (3) certified repairs performed by inspectors with lapsed credentials. See Grant, 2018 WL 6786134 at *1. The relator argued the subcontractor “knowingly present[ed], or caus[ed] to be presented, a false or fraudulent claim for payment or approval,” in violation of 31 U.S.C. § 3729(a)(1)(A), and “knowingly ma[de], us[ed], or caus[ed] to be made or used, a false record or statement material to a false or fraudulent claim,” in violation of 31 U.S.C. § 3729(a)(1)(B). Grant, 2018 WL 6786134 at *2. “Therefore, a central question in all [False Claims Act (FCA)] cases is whether the defendant ever presented a false or fraudulent claim to the government, resulting in a ‘call upon the government fisc.’” Id. at *3 (quoting Harrison v. Westinghouse Savannah River Co. (Harrison I), 176 F.3d 776, 785–86 (4th Cir. 1999)). After reviewing its precedent in Nathan, the court of appeals explained there are two ways to adequately plead presentment under Rule 9(b)’s heightened pleading standard.

First, a plaintiff can allege with particularity that specific false claims actually were presented to the government for payment. This standard requires the plaintiff to, at a minimum, describe the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby. Alternatively, a plaintiff can allege a pattern of conduct that

would necessarily have led to submission of false claims to the government for payment.

See id. at *3 (internal citations, quotations, and brackets omitted). Because the relator's complaint failed to identify a specific false claim presented to the Air Force for payment, the Fourth Circuit considered whether the relator was able to allege "a pattern of conduct that would necessarily have led to a false claim being submitted." Id.

The Grant Court reasoned that, while the relator *had made* sufficiently particular allegations to allege the subcontractor "engaged in at least some fraudulent conduct," the complaint failed to provide the critical last link: "namely, that this scheme necessarily led to the presentment of a false claim to the government for payment." Id. at *4. Specifically, the court took issue with the attenuation between the contractor's misconduct and billing to the federal fisc:

Merely alleging fraudulent conduct and an umbrella payment, without more, is insufficient particularly where, as the SAC itself alleges, United is three levels removed from the Air Force, which contracts directly with Boeing. By contrast, in Lusby and Lockhart, cases on which Grant relies, the defendant contracted directly with the government, and the complaint provided at least some explanation of the billing structure. See, e.g., United States ex rel. Lusby v. Rolls-Royce Corp., 570 F.3d 849, 854–55 (7th Cir. 2009) (satisfying the presentment requirement where the defendant directly contracted with the U.S. military and received payment for non-compliant engine parts); United States ex rel. Lockhart v. Gen. Dynamics Corp., 529 F.Supp.2d 1335, 1336, 1341 (N.D. Fl. 2007) (satisfying the presentment requirement where the defendant sold ammunition propellant directly to the U.S. military and the relator had first-hand knowledge that required tests were not completed). *Absent some explanation of the billing structure or how or whether the government paid for repairs in this subcontracting scheme, Grant has not shown that false claims were necessarily presented to the government for payment for two reasons.*

Id. (emphasis added). The appeals court explained the complaint left open the possibility the government was never billed for the fraudulent services or, even if the relator had properly alleged the government was billed, that defects in the service were remediated by the prime or subcontractor that stood between the defendant and the government. See id. at *4–5. Thus, drawing

on language first used in Nathan, the Grant Court found the claim to be one that “*could* have led to presentment,” but did not “*necessarily* le[a]d to a false claim being submitted to the government for payment.” Id. at *5 (emphasis original).

The Complaint here meets the standard described in Grant. Without (again) reciting the operative facts (see Dkt. No. 66 at 2–4), the crux of MiMedx’s patient assistance program (PAP) grant scheme is MiMedx’s effort to obtain and fund grants for patients who would not otherwise be able to meet coinsurance obligations under Medicare Part D, while manipulating the submission of PAP grant applications to ensure MiMedx’s so-called charitable contributions only fund grants that facilitate Medicare reimbursement for MiMedx products. Unlike Grant, where an intervening act or actor might have vitiated the possibility of presentment, no presentment would occur here (fraudulent or otherwise) unless MiMedx sales representatives (reps) were engaged in preparing and submitting PAP grant applications—a critical component of the illicit kickback scheme. Put differently, the allegations *necessarily* resulted in the submission of false claims because the entire thrust of the scheme is to obtain reimbursement by a federal health insurance program.

The holding in Grant does not alter the relevant standard here; it reinforces the conclusion that Mr. Vitale’s allegations exceed what Rule 9(b) requires while clarifying that claim-identification or first-hand participation in billing operations has never been the only way to meet FCA pleading obligations. See Grant, 2018 WL 6786134 at *5 (discussing Lusby, 570 F.3d at 854; United States ex rel. Harrison v. Westinghouse Savannah River Co. (Harrison II), 352 F.3d 908, 921–22 (4th Cir. 2003)). Instead, “Rule 9(b)’s heightened pleading standard requires that plaintiffs connect the dots, even if unsupported by precise documentation, between the alleged false claims and government payment.” Id. at *5. Mr. Vitale’s Complaint meets that standard.

CONCLUSION

For these additional reasons, and those explained in his memorandum in opposition, the motion to dismiss should be denied.

Respectfully submitted by,

s/Christopher P. Kenney
Richard A. Harpootlian (Fed. ID No. 1730)
Christopher P. Kenney (Fed. ID No. 11314)
RICHARD A. HARPOOTLIAN, P.A.
1410 Laurel Street
Post Office Box 1090
Columbia, SC 29202
Telephone: (803) 252-4848
Facsimile: (803) 252-4810
rah@harpootlianlaw.com
cpk@harpootlianlaw.com

William N. Nettles (Fed. ID No. 6586)
Frances C. Trapp (Fed. ID No. 6376)
Bill Nettles, Attorney at Law
2008 Lincoln Street
Columbia, South Carolina 29201
(803) 814-2826
bill@billnettleslaw.com
fran@billnettleslaw.com

ATTORNEYS FOR RELATOR JON VITALE

January 2, 2018
Columbia, South Carolina.